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Revised

LESSONS LEARNED

PROVIDING TECHNICAL ASSISTANCE IN THE REFORM OF HEALTH CARE LAWS AND REGULATIONS IN RUSSIA

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INTRODUCTION

The following nine "Lessons Learned" are derived from four years of experience with a succession of three USAID financed Cooperative Agreements to assist in the development of legal and regulatory reforms in health care in Russia. We believe that the lessons have applicability to legal assistance in the health sector in other CIS countries. It is harder to say if they would apply to reform where the laws are different, the health care system is much smaller (in terms of staffing and the facility base), or where public health and health finance have evolved very differently.

1. DO NOT PROVIDE TECHNICAL ASSISTANCE UNLESS THE COLLABORATING AGENCY INDEPENDENTLY INDICATES THAT THE PROJECT IS A PRIORITY. ("Svetlana's law").

As project managers, this is our most important rule. It is named after the first project director, Svetlana Kruchinina. Svetlana insisted that a collaborator indicate, in writing, its interest in the reform, and in receiving technical assistance to develop the law or regulation. It is too easy for an agency to offer to cooperate, particularly when there are apparent financial rewards to doing so. A written commitment to work together means that the counterpart agency is publicly committed to considering the reform. The agenda for reform is the agency's, not the advisors.

This does not mean that the counterpart is, in any way, binding itself to take the suggestions offered by Project advisors. But it makes it difficult to totally ignore these suggestions. The independent commitment to consider the innovation (draft law, regulation, reform concept) means that the counterpart is prepared to address the issues, even if it rejects the consultant's advice.

The fact that a counterpart agency indicates an area in

which it is willing to act does not commit the Project to work in that field. In working with the Duma Health Care Committee, we asked for the listing of priority reforms, then selected from this list. In other cases (such as the Federal Mandatory Health Insurance--"MHI"--Fund), we informally discussed the counterpart's areas of interest. The Project responded, limiting its offer to the areas where the Project had expertise and interest. We then agreed in writing on a scope of work for the joint effort. Similarly, in the oblasts, we selected from a list of legislative priorities offered by the oblast.

In one or two cases, the oblast backed away from an initial commitment. The Kaluga oblast Duma lost interest in a patient's rights bill which the Project initially supported. Most agencies followed through to the completion of a draft law or regulation.

The commitment should come from the organ of government which will be responsible for the reform. Thus, with regulations, it should be the agency which will issue the regulation. Wherever possible, any agency that must approve the promulgation of regulations should be included in the commitment.

Even when a responsible Duma committee commits to a reform concept, the necessary political support may not develop. There is little a project can do about this. However, to enact a law, the support of the legislature as well as the administration must be obtained. In two cases, good draft laws have yet to pass because the active support for collaboration came from the Health Committee and/or the oblast MHI Fund, but not from the oblast Duma or the oblast Finance Department. The draft Kaluga health financing law includes a very innovative concept that would permit copayments when public funding for the minimum benefit package is inadequate. It would also punish providers that collect informal payments when public funding is adequate. The oblast Duma was unwilling to take such a realistic approach. In Moscow oblast, the Health Committee enthusiastically developed a draft bill with reimbursement formulae that would reduce barriers to the movement of patients between municipalities in order to obtain specialist care. However, the oblast Finance Department refused to support the bill because it feared a loss of budget control.

2. THE TWO STEP MODEL USED IN RUSSIA FOR DRAFTING REFORMS IS A GOOD ONE. (First a "conceptsia," then a draft law.)

Rather than launching directly into legalisms, or being bound by existing legal forms, the Project's working groups began

by developing a conceptsia, a white paper explaining what the new law or regulation should accomplish. In effect, the policy was decided before the drafting of the law began. Contentious issues were debated on their merits, rather than arguing about "language" or legality. We found this the best way to air the issues. The conceptsia is a much more "user friendly" document for public discussion and debate than a draft law, which is dry and legalistic.

Once a conceptsia is agreed, a competent lawyer can be hired to draft the actual implementing legislation. While there may be some arguments over language, the drafting process goes much more smoothly.

Sometimes, there seemed little difference between the conceptsia and the law, with the draft law carrying forward some of the more ambiguous or policy-oriented language in the conceptsia. To an American draftsman, the Russian bills seemed vague at times. Nonetheless, where the system worked best---as it did with the private practice law---the two step process succeeded when an attempt to proceed direct to legal drafting might have faltered for lack of consensus.

3. IN A LARGE AND DIVERSE COUNTRY, ENCOURAGE LEGAL EXPERIMENTATION AT THE SUB-NATIONAL LEVEL. (As in the U.S., there is a reason to call the states (oblasts) a "laboratory for democracy.")

If success is defined as a law, regulation or administrative innovation adopted and in force, most of the Project "successes" after four years are out in the oblasts:

- . Samara private practice law
- . Novgorod pharmaceutical law
- . Novgorod financing law
- . provider reimbursement experiments in Samara (Know How Fund), Maroyaroslavets (teamed with KPI), Tula (a current project grantee)
- . proposed specialist hospital outpatient departments in Petersburg (a current grantee). Part of a reform that could move from the current polyclinic structure to a primary care/ hospital specialist system that should be less costly and of higher quality)

Although smaller in population, Russia is more geographically and economically diverse than the United States. The difference in per capita income or local financial capacity between Moscow and a poor oblast is greater than that between New

York and any state. Policies which will work in the long run must recognize these differences. Ultimately, Federal revenue should be used to reduce the large disparities in capacity to support health (and other services).

Despite the devolution of fiscal responsibility, the health system in Russia maintains a certain delusion of central control.

This legacy of centralization sometimes inhibits reform in the oblasts. To the extent that Federal standards and policy imperatives are updated, such changes should reflect knowledge of "what works" in the oblasts.

Even where the Project worked well with a federal agency---as it has with the Federal MHI fund----the innovations have actually been implemented at the oblast level. Some oblast MHI Funds adopted certification standards for insurers participating in MHI while the Federal government dithered about promulgating the regulations developed by the Federal Fund. Individual oblasts have expressed interest in experimenting with capitation-based payment procedures and "global budgets" for hospitals at the same time that the Federal fund is pulling back from the December 1999 drafts encouraging these developments.

Inertia at the Federal level is not surprising. In the U.S., major social reforms are often tested in the states before becoming national policy. Before mandating a national policy, it is advisable to experiment with new ideas at the sub-national level. This requires reform minded administrators in the oblasts. It also requires independent researchers who can objectively evaluate the impact of these reforms (see Lesson Six below). For example, the apparently successful experiment with primary care provider reimbursement in Maroyaroslavets has been attacked by Ministry of Health opponents because it did not consider the possibility that death rates might have increased outside the remaining hospital beds. The cost savings in Maroyaroslavets deserve careful national consideration, and that includes a full INDEPENDENT assessment of costs and benefits, including any negative impacts on patient outcome.

4. REFORMS SHOULD PROCEED IN EASILY DIGESTED INCREMENTS. (Beware the "omnibus" reform bill).

One of the Project's disappointments has been the "Law on the Structure of Health Care in the Russian Federation" (the so called "Structure Law.") This has been a favorite of Dr. Gerasimenko, the Chair of the Duma Health Care Committee. He originally asked the Project for advice on topics to include in a

"Codex" of health care law. He intended to seek a comprehensive recodification of all Russian laws related to health care. Although they developed a comprehensive listing of topics covered in health legislation, Project advisors warned Dr. Gerasimenko that reform laws in other countries deal with only one aspect of health care---public health, health services financing, licensing, the structure of government responsibilities. In most cases, a reform law deals with a subset of one of these categories.

Dr. Gerasimenko recognizes that Soviet era health laws are grossly outdated. Funding had been decentralized, the power of the Federal Ministry of Health had dwindled, and health insurance introduced a new source of funds---and confusion---into the health care system. However, even when limited to defining responsibilities for health care provision and financing, the proposed Structure Law encountered enormous legislative resistance. Despite the high levels of private payment in many government facilities, Communists oppose any section legitimizing and regulating the private practice of medicine. The Finance Ministry opposes the law's optimistic targets for public funding of health care. Dr. Gerasimenko is reluctant to introduce any sections providing for more autonomous management of health care facilities for fear of increasing the opposition to the bill. With so many facets, there is something in the draft for each party at interest to dislike. As a result, the Structure Law has not moved beyond first reading more than three years after drafting began.

The political logjam in the Duma which stalled the Structure Law also impeded the progress of narrower reforms, such as the proposed Tuberculosis Law. However, the changes demanded in the first draft of this more limited bill are more amenable to clever drafting and political compromise. If the Structure Law passes at all, it will likely be a shadow of the original draft. For this reason, we recommend that draft reforms be carefully targeted and limited in scope.

More sweeping and radical laws passed the Duma earlier in this decade. The passage of the health insurance law was a landmark. Although it has many inadequacies, it keeps the level of public funding for health services above that in most other CIS countries. In the first flush of reform of the early 1990's, it may have been possible to legislate more sweeping changes in a single law. But now the conditions are different. With poorer health outcomes, citizens and the opposition are understandably reluctant to take actions which might damage the health care system further. With few non-governmental providers, there is no locus of power to support changes in the status quo. Thus, it is

necessary to develop a coalition around more narrowly defined changes, to effectively market the benefits of such reforms (hopefully, with real data from oblast experiments), and to focus on the passage of the most important incremental reforms.

5. MORE RADICAL REFORMS REQUIRE A LONGER TERM COMMITMENT TO BACKGROUND RESEARCH AND THE DEVELOPMENT OF ARGUMENTS WHICH CAN CHANGE THE "CONVENTIONAL WISDOM." (Do not expect rapid, sweeping reforms, except in the most dramatic of circumstances.)

Even in the chaos which characterizes the Russian health care system today, there is limited willingness to innovate. Having observed the seizure of much Russian industry by "vulture" capitalists, it is understandable that many Russians are unwilling to encourage new forms of ownership or management in health care. Clinging to the admirable principle of free medical care enshrined in the Constitution, policy makers were reluctant to recognize the barriers to access created when health institutions charge patients for services without reference to need or the ability to pay. No project can hope to address these problems with laws quickly drafted and passed. To implement more extensive financial or organizational reforms, there must be a longer period in which three things happen:

- . data is developed which shows the depth of the problem
- . policy makers are exposed to reforms operating in other countries which are effective in those environments
- . variants of these reforms are developed and legitimized in policy debate within Russia.

It takes years for these three things to happen. We give two examples from Project experience.

Although allowing that there is some "private payment" in the health system in the form of gratuities, policy makers refused to believe that the total of private payments was significant or might seriously restrict patient access. For this reason, the Project undertook the household health expenditure studies. These surveys show that private payment equals or exceeds total public health expenditure. Private payments are a significant barrier to care for the poor. Drug purchases by consumers are particularly regressive. Now, two years after the initial survey report, we can see that these facts have begun to influence the policy debate. As a candidate, President Putin acknowledged in one statement that Russians are paying half of their health care costs. Dr. Starudobov, then Health Minister, tried to address the problem of drug costs in the "oriental

bazaar" (Dr. Gerasimenko's words) of the Russian pharmaceutical market. The Putin strategy center sought suggestions on ways to reduce the barriers to necessary care which are created by private payments.

Another example of the need to take the long view in reform is our experience introducing concepts of more autonomous management (and perhaps non-governmental ownership) for existing health facilities. Although many Russian health managers express admiration for the kind of management autonomy available to American non-profit health care organizations, or British hospital trusts, there was no willingness to introduce such a radical concept into the Structure Law. A separate working group on alternative organizational forms has now examined both Russian law and foreign precedents. The group concluded that existing Russian law has no adequate form, and recommends a new form which would prevent diversion of existing public resources from health care while granting more management autonomy to health care institutions. It would be a Russian adaption of the British Trust model. With this paper complete, it may now be possible to build support for a reform which permits health facility managers to redirect resources within the health care system. While it may take several more years before such a law could pass and be implemented, the Project was heartened in June of 2000 when the Putin Administration included drafting of such a law in its legislative agenda.

The long gestation period for these ideas shows that a technical assistance project cannot expect to foster major legal changes in a short period of time. Furthermore, the technical assistance provided must be more than clever lawyering. To encourage these broader reforms, the Project must be patient. It must fund research which will provide empirical data as ammunition for the reformers. And it must allow time and resources to adapt foreign precedents to the local situation and build understanding of these ideas among policy makers who are conservative and skeptical of the "benefits" of recent changes in other economic sectors.

6. IN THE LONG TERM, SOUND REFORM REQUIRES THE DEVELOPMENT OF HEALTH POLICY ANALYSIS CAPACITY WHICH IS INDEPENDENT OF GOVERNMENT.

This is, in effect, a corollary to Lesson Five. The CIS countries have no history of independently commissioning health services research or policy analysis. To the extent such work was done, it was done by institutions with close affiliations

with the Ministry of Health (such as MedSocEcnonInform). There is no tradition of competitive research funding, nor any source of funds to support research which is not on a "government agenda."

An example from our experience: Despite the obvious inadequacy of current public funding for health care, no Russian agency developed data on the impact of out-of-pocket health care expenditures. The Project was fortunate to be able to fund this research. The surveys should be continued after the end of the Project, but this is unlikely unless independent "think tanks" develop and a source of funds is available to these organizations. A long term investment, perhaps creating an endowment for such institutions or research, would provide a lasting contribution to health care reform.

Another example: No Russian government agency has yet (so far as we know) tested the knowledge of its own providers about the laws governing the diagnosis and treatment of HIV patients. The Federal HIV law is, in general, a good one. However, until the focus groups commissioned by this Project, no research had been done on the way in which laws (and general knowledge) affect the way Russian doctors deal with HIV/AIDS patients.

In addition to financial support, there should be a "home" for policy analysts and researchers who do not have a vested interest in the existing health care system. We found the Federal MHI Fund closely tied to the interests of the insurers, the Ministry of Health reluctant to challenge the existing government-dominated structure for the provision of health services. When Candidate Putin's staff sought advice on more radical reforms in health care (particularly those addressing the inadequacy of current public funding), it turned to the Moscow Project Director and one of his associates, who works for the Gaidar institute.

The need to create and endow independent institutions for policy analysis in economics or the environment is more clearly accepted than in health care. Perhaps this is because the Government continues to dominate the provision of health care services, and there are few non-governmental providers or advocacy groups in health. Nonetheless, health should be a priority for the development of non-governmental policy analysis. In the long run, independent institutions could replace funding from foreign assistance with competitive research grants or contracts, unrestricted fund raising from major players in the health and pharmaceutical market, and consulting fees to the institutions or their principals. Fund raising should not influence the independent research agenda or the attitudes of the

researchers. This balancing act will be difficult. But in the absence of independent health policy analysis and health services research, it will be very difficult to propose new ideas or evaluate those innovations that are tried.

7. A CAREFULLY DRAFTED MEMORANDUM IS MORE VALUABLE THAN MANY PAGES OF TEXT FROM ANOTHER COUNTRY'S LAWS. (Do not go into the details of another country's statutes or regulations until it is clear that the text can solve a particular drafting problem).

Our Russian colleagues agreed that the most valuable foreign assistance provided by the Project were the "background memos" which Boston University staff prepared on the issues to be addressed in draft laws or regulations.

Laws are difficult to comprehend in the reader's own language. When presented in translation, they can be both soporific and confusing. Many of the concepts addressed by health reform are new to the law in a country like Russia. Therefore, the major foreign effort should go into explaining the issues, and the alternative resolutions of these issues in other countries. Undigested extracts from other laws are likely to be ignored, or misunderstood. After the first draft of a reform law is complete, it may be appropriate to offer carefully selected excerpts from other laws which solve a particular drafting problem, such as the precise definition of a key term. For example, as one working group examined ways to keep non-governmental health providers focused on public purposes, the Project provided examples from the language of U.S. state laws which hold non-profit organizations accountable to their public purposes.

8. A SHORT CAREFULLY TARGETED MEMORANDUM, PROMPTLY DELIVERED, IS MORE EFFECTIVE THAN A LARGE HANDSOME REPORT WITH A LONG GESTATION PERIOD.

As lawyers say, advice is best when it is "on point." And immediately available to a debate. We found that the advisor's leverage was greatest when the Project responded promptly with a narrowly focused memorandum on a question posed by a working group or a government official. While these memoranda should have solid intellectual content, excessive polishing which delays delivery to the client reduces effectiveness. The client will usually only read the document after it has been translated, so excessive production values are lost.

An example of this point is seen in a project activity that "never happened." Russian government officials approached the Moscow Office Director asking for information on a Federal law which would encourage citizens to change their behaviors and reduce health risks. In part, they seemed to be operating under the naive assumption that a single Federal statute can motivate, if not coerce, a broad change in individual behavior. The Russian officials were also under the impression that a U.S. Federal statute explains the American emphasis on healthy behaviors (reduced smoking and alcohol consumption, better diet and exercise, lower traffic fatalities). The Russians also expected that U.S. efforts to reduce cancer incidence must have been codified into a single Federal law. In a very short period of time, the Project provided memoranda indicating that the U.S. has no single law which explains changes in risky behavior or cancer mortality. The memo explained that successes are tied to a complex combination of different state and federal laws, as well as efforts by non-profit groups, the medical profession, and the press. The memorandum cited examples from local anti-smoking ordinances to the Surgeon General's report on smoking to tobacco taxes to the successful efforts of Mothers Against Drunk Driving.

The memorandum concluded that there are no monolithic statutory answers. This response appears to have diverted the Russians from trying to draft a single comprehensive statute that would not have motivated changes in individual behavior. Over the long run, we hope that our advice will contribute to the education of Russian policy makers on the complex factors, including grass roots non-governmental initiatives, which are necessary to encourage citizens to change their behavior in ways that will increase life expectancy.

We have documented our work by attaching the memoranda to quarterly progress reports. When there is a "set piece" that is useful for wider publication in English---such as the results of the household health expenditure survey-----more elaborate report preparation is justified. The Interim Evaluation of the Project commented with disapproval on the absence of well produced reports for wider distribution. As a response, we are trying to improve the research reports. But for legal advice, quick response with a well translated "on point" memo is the most effective way for foreign advisors to influence a debate.

9. SPECIAL WORKING GROUPS ARE AN EXCELLENT FORUM FOR CONSIDERING REFORMS (Generally better than trying to provide foreign input

directly to existing bureaucratic structures).

In almost all our projects, the collaborating agency convened a working group to discuss the reform. This usually included interested parties outside the responsible agency. Most national level working groups included representatives from oblast health committees or territorial MHI funds. One or more Russian consultants from the Project sat on the working group.

The Project provided input to the Working Group, including examples of relevant laws and regulations from other countries, and memoranda summarizing the issues and possible alternative resolution of such issues. Occasionally, a foreign consultant would meet with a working group early in the process to discuss basic issues and concepts. When the working group produced a draft (often written by a Russian lawyer funded by the Project), the US technical advisors reviewed the draft concepts or law in detail, and summarized their suggested changes in writing. The interim and final drafts were clearly Russian products, not documents crafted by foreign consultants, or even by the Project's Russian managers.

In commenting on concepts or laws, we did not hesitate to identify sections with which we disagreed on economic or policy grounds. Sometimes these objections resulted in agreement by the working group to modify the language of the initial draft.